

### **Washington Office**

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## **United Egg Producers**

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	September 30, 1999	
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Dockets Management Branch, HF-305		
Food and Drug Administration		, <sub>4</sub> :
5630 Fishers Lane, Room 1		
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Rockville, MD 20852		

#### Docket No. 98N-0359

Dear Sir or Madam:

United Egg Producers (UEP) is pleased to comment on Program Priorities for the Center for Food Safety and Applied Nutrition, Docket No. 98N-0359. UEP is a federation of regional cooperatives owned and operated by egg producer members. UEP's membership represents the ownership of about 80% of all the egg-type laying hens in the United States as well as most of the major breeding companies. UEA represents approximately 95% of all further processed eggs in the U.S., amounting to more than two billion pounds per year.

The egg industry has supported, and continues to support, programs in food safety. The Center for Food Safety and Applied Nutrition's (CFSAN) emphasis on food safety is an appropriate and important priority. Likewise, the cross-cutting areas listed in the September 1, 1999 Federal Register notice are also important as is a program area in nutrition. Additionally, food safety research and food safety education are central to the ability to control foodborne disease. Perhaps most important to the needs of a regulatory agency is to have programs that result in the enforcement of regulations in an even-handed fashion using good reason and common sense. Incentives, as well as sanctions, must be part of effective regulatory programs.

The egg industry has particular concerns about selected food safety issues. Foodborne disease outbreaks and trace-backs need to be accurate and fair. Messages on egg cartons need to benefit the consumer by stimulating constructive changes in egg handling practices, not merely causing undue alarm. Eggs need to be kept cool everywhere in the food chain. A coordinated, unified grading and inspection program for eggs (including financial compensation to the producer

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for testing costs) would benefit both consumers and producers and help ensure a safe food supply. Finally, safe food production needs to be accompanied by safe food preparation. Education is an essential part of this goal.

Foodborne disease outbreaks, and the associated trace-backs, can be an opportunity for increasing our understanding and controlling foodborne disease. However, the outbreak investigations need to be thorough and accurately identify the responsible food vehicle. In addition to the epidemiological investigation, microbiological analyses need to be included as well as investigation of the environmental factors that led to the outbreak. Resources, training and funds need to be provided to the local governments, who have the responsibility for these investigations. Of equal importance is the procedure for conducting a trace-back; it needs to be accurate, fair, and based on published procedures. The current trace-back program for eggs is ineffective. The industry recommends that it be eliminated or modified. A logical, reasonable policy with an established and written protocol is needed. UEP suggests the plan attached in appendix A. Additionally, since not all Salmonella Enteritidis outbreaks are caused by eggs, trace-backs on non-egg outbreaks should also be conducted.

Labeling egg cartons with food safety information will be productive only if the messages are understood, remembered and acted upon. "Warnings" often simply push the consumer away without changing their food preparation practices. In-depth consumer research is needed to ascertain what words or pictures are needed to motivate the consumer to prepare food safely. The Fight BAC! logos may best accomplish this goal as UEP pointed out in separate comments filed with this agency on September 17, 1999.

Continual refrigeration of eggs will help to ensure that in the infrequent event that bacteria is present inside a shell egg, that it will not multiply. The egg industry sought the requirement for refrigeration of shell eggs, across the nation, during storage and transportation. Even-handed enforcement of refrigeration in groceries and at other food service institutions is needed to extend and ensure the protection that is initiated by the producer.

A unified system of grading and inspecting eggs (Appendix B) should be considered as part of the federal strategic egg safety program that is being developed. A coordinated and comprehensive program, applied evenly across the nation, is needed to ensure food safety. Providing financial compensation for producers who are testing would serve as an incentive for good production practices and participation in quality assurance programs.

Food safety education should be a fundamental part of public education. Although "clean food" must be produced, even pasteurized or sterile products can transmit disease if stored or prepared improperly. As food is essential to life, knowledge of safe food preparation practices should be widespread. Recommendations for safe egg storage and preparation practices should be developed in coordination with the egg industry, which can also assist in developing educational materials.

CFSAN has proposed certain questions. The issue that directly affects consumer safety that is not being addressed adequately is that of determining the vehicles and agents that cause foodborne outbreaks. Food safety policy decisions and priorities continue to be made on a data base that is only 40% complete. This is woefully inadequate. The activities listed above should be among CFSAN's priorities. The most important research topics are understanding consumer behavior and developing analytical detection techniques. Research on consumer understanding and response to messages is needed to ensure that the consumer understands what actions can be taken to protect his or herself. The ability to detect pathogens is key to protecting the food supply. With regards to international needs, the egg industry supports the need for harmonization and the development of transparent and science-based policies.

UEP appreciates this opportunity to comment on program priorities in the Center for Food Safety and Applied Nutrition.

Yours sincerely

Ken Looper Chairman

Ken Klippen Vice President.

Government Relations

President

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**Enclosures** 

Appendix A - Protocol for S.E. Traceback As Proposed by United Egg Producers

Appendix B - Egg Quality and Safety: Toward a Cooperative Approach

# PROTOCOL FOR S.E. TRACEBACK

#### AS PROPOSED BY UNITED EGG PRODUCERS

When a public health investigation uncovers food handling abuses, food service workers carrying the S.e. bacteria, cross contamination, etc., a traceback to the farm should not be warranted.

- 1. If a traceback is deemed necessary then shipping records or other evidence will be required which assures the producer and FDA that eggs from the producer's flock was the source that caused the human illness outbreak.
- 2. An outbreak investigation report should be provided to the producer by the FDA or the State Health Department before any testing is conducted of the producer's facilities. The investigation report should include the phage type of S.e. that caused the illness. (If upon investigation, the same phage type is not found on the farm, then it must be concluded that the farm was not the cause of the human illness.)
- 3. Confidentiality and media avoidance should be guaranteed to the producer until proven results are known.
- 4. In consideration of the fact that an egg producer can not hide evidence such as the poultry house, chickens, or eggs, any producer that may be implicated in a human illness outbreak will be given a minimum of 48 hours notice before FDA or State Health Departments arrive at the farm.
- 5. A federal standard of traceback protocol should be written and followed by both FDA and State Health Departments and a copy provided to the egg producer prior to any testing of the producer's facility.
- 6. In recognition that producers have used every means known to control S.e. and to encourage more producers to use such programs, FDA will end the traceback if the investigations finds either one of the following conditions:
  - (a) For those farms implementing a Quality Assurance/Food Safety program that includes vaccinations for S.e., the investigation will be considered complete. If, however, FDA determines that the investigation should continue, then the environmental tests will be eliminated and go directly to egg tests.
  - (b) For those farms implementing a Quality Assurance/Food Safety program that includes validation testing of the program and has tests results indicating an S.e. negative environment at the approximate time of the

human illness outbreak and recordkeeping that all components of the program are being monitored, will be exempt from environmental testing of the facilities and egg testing by FDA or State Health Departments.

- 7. If it is determined that a traceback is warranted, the investigation should first determine whether a Quality Assurance/Food Safety program has been implemented by the producer. Farms that have not implemented a Quality Assurance/Food Safety program and have been implicated in a human illness outbreak will be expected to cooperate with FDA or State Health Departments in a traceback that includes testing of the environment or of the eggs.
- 8. Environmental testing is not an accurate predictor of the status of the eggs. Eggs, however, from the layer house should be diverted to pasteurization or hard cooking until test results are known of the eggs.
- 9. Environmental testing should only be taken from manure pits. In the absence of manure pits, swabs from the manure belts or scraper boards may be used.
- 10. Eggs from environmentally positive houses should be tested at the rate of 1% of one day's production regardless of the size of the individual layer house.
- 11. Eggs from environmentally positive houses should be diverted and egg testing should be conducted as many times as necessary until the first S.e. negative test report is confirmed. No further testing or diversion should be required.
- 12. Producers whose layer house is found to be environmentally S.e. positive must agree to implement a Quality Assurance/Food Safety program immediately. The producer shall have the right to implement any Quality Assurance/Food Safety program so long as the program has the ability to directly address the problem.
- 13. Houses that have been tested as environmentally S.e. positive, must upon depopulation of the flock, take extra steps in their cleaning and disinfecting procedures. A third-party inspection of the facility should be conducted. This third-party inspection may be conducted by representatives from any of the following:

State Veterinarian
USDA/AMS Poultry Grading Service
USDA/APHIS/VS

Submitted to FDA – May 1999

# EGG QUALITY AND SAFETY: TOWARD A COOPERATIVE APPROACH

The United Egg Producers look forward to working with federal regulatory agencies and other interested parties to explore initiatives to address the presence of *Salmonella* Enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. Egg producers are prepared to take on new responsibilities in order to ensure that the public interest is served. They also believe strongly that the public must be prepared to recognize the strong national interest in safe, high-quality food through the investment of public funds.

Recent data from FoodNet and other surveillance systems demonstrate significant reductions in the incidence of salmonellosis caused by SE. However, both regulatory agencies and the public perceive a need to make further progress in combating this pathogen. The egg industry has taken numerous steps to improve the quality and safety of its products. Producers are conscious of both the need for further improvements and the substantial costs that could be involved for an industry suffering from the low commodity prices that afflict almost all of U.S. agriculture.

#### Components of a Comprehensive Approach

The board of directors of United Egg Producers have instructed UEP staff to explore a comprehensive approach to egg quality and safety. The UEP board has made no final decision on any particular proposals. However, a broad strategy might comprise the following elements:

- A uniform national inspection and quality assurance program administered by USDA/AMS
- The deployment of Department personnel for inspection based on actual performance and experience in each facility;
- Industry-wide requirements governing the maximum number of days after an egg is layed that it can be packed;
- An industry-wide standard "sell-by" date on consumer packages that is easily understandable:
- Quality assurance programs based on HACCP principles at production and packing facilities:
- Establishment of a system for documenting, validating and verifying producer compliance with quality assurance programs;
- Development of a uniform written protocol for traceback investigations by the Food and Drug Administration;
- As a component of the uniform national system for inspection and quality assurance, the development of appropriate protocols for disease prevention, structured to be adaptable to technological and veterinary advances, with consideration given to testing, vaccination and other approaches;
- Indemnification of producers for any requirements to divert production to less-valued uses or to take other measures;
- Liability protection for producers who comply with provisions of the uniform national

- system of inspection and quality assurance;
- The appropriation of sufficient funds to carry out all the Department's responsibilities under the comprehensive egg safety program, including the payment of indemnities and all costs of the inspection and quality assurance program, just as present Department activities to inspect meat, poultry and egg products are paid from appropriated funds;
- Refrigeration of shell eggs during storage and transportation and at retail;
- Enhanced educational and regulatory initiatives to encourage proper handling and preparation of eggs and egg-based dishes in food service establishments and institutions;
- Enhanced educational outreach to consumers to encourage proper storage and preparation at home;
- Uniform federal standards to ensure safe products and safe preparation of eggs and egg dishes in institutions serving at-risk populations;
- Development of consumer labeling provisions for retail egg cartons, and separate labeling provisions for containers intended for food service use, that convey appropriate information in the most effective form to reduce disease but are crafted to avoid alarmism.

#### Fundamental Principles

The egg industry is prepared to take additional steps to ensure that consumers can enjoy eggs with confidence in their safety. However, the industry strongly believes that these steps must –

- Be part of a comprehensive approach that resolves as many outstanding issues as possible, so that producers can conduct their businesses with certainty about the regulations under which they will operate;
- Treat all egg producers equitably, providing uniform national incentives for product quality and safety;
- Recognize the progress already made by the industry at the national and state levels;
- Avoid imposing another financial burden on U.S. production agriculture at a time of depressed prices and low farm income;
- Be the result of a cooperative effort between producers and regulators, so that decisions are not only comprehensive but practicable and economical; and
- Involve a federal commitment of the funds necessary to serve the public interest properly and effectively, providing appropriate incentives to producers and other interested parties.

If these principles guide our decisions and actions, the interests of producers and consumers alike will be well-served.